

SEP 21 2007

K072244
Pg 1 of 2**510K) SUMMARY****DATE**

August 28, 2007

PRODUCT, CLASSIFICATION NAME

Trade name: Planmeca ProOne

Common name: Panoramic x-ray system

Classification: 76 EHD, Class II

Regulation number: 872.1800

MANUFACTURER

Planmeca Oy

Asentajankatu 6

FI-00880 Helsinki, Finland

Phone: +358 20 7795 500

Fax: +358 20 7795 396

Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)

Planmeca USA Inc.

100 North Gary Avenue, Suite A

Roselle, IL 60172

Phone: (630) 529 2300

Fax: (630) 529 1929

Contact person : Bob Pienkowski

INTENDED USE

Planmeca ProOne, is a dental panoramic x-ray imaging system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is digital, and the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer. The device is to be operated and used by dentists and other legally qualified professionals.

PRODUCT DESCRIPTION

The Planmeca ProOne is a conventional panoramic x-ray system utilizing the digital imaging method. The tube head assembly and sensor rotates around the patient and takes a dental panoramic image of the patient. The product is a new model, with simple and reliable design, but with all necessary functions included. The computer is linked to the device via Ethernet.

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SUBSTANTIAL EQUIVALENCE

We consider this new product to be similar in design, composition and function to the following devices introduced into commercial distribution after May 28, 1976:

- # K000454 Planmeca Proline with Dimax 2
- # K051464 Planmeca Promax with DEC

The comparison of characteristics supports substantial equivalence. Planmeca ProOne is as safe and effective as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 21 2007

Mr. Lars Moring
Regulatory Affairs Manager
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki
FINLAND

Re: K072244

Trade/Device Name: Planmeca ProOne
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 8, 2007
Received: August 13, 2007

Dear Mr. Moring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072244

Device Name: Planmeca ProOne

Indications For Use:

Planmeca ProOne, dental panoramic x-ray imaging system, is an extraoral source x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is digital, and the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer. The device is to be operated and used by dentists and other legally qualified professionals.

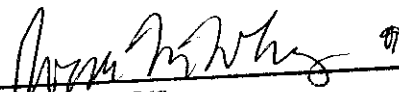
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072244

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